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OCT 25 2010

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER 37 CFR 41.52 Rehearing**

Application No.: 10/812,380

Filing Date: March 29, 2004

Date faxed: April 16<sup>th</sup> 2009

Applicant: Iftikhar Khan , Nazir Khan

Group Art Unit: 3761

Examiner: Leslie R. Deak

Title: HYBRID ARTERIOVENOUS SHUNT

Attorney Docket: 1800-000001

Mail Stop AF

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**APPLICATION NO. 10/812,380**  
**APPEAL NO. 2010-003194**

**37 CFR 41.52. Rehearing**

The appellants request for rehearing of the appeal before the board of patent appeals and interferences for the following reasons:

1. Combining the prior arts of Squitieri, Parks et al and Twardowski does not teach claimed invention and will result in the destruction of the function of claimed invention and that of prior art of Squitieri.  
Parks invention consists of connector which is to be disposed within the inlet end of the conduit (column 3, line 10). The connector is made of hard substantially non-deformable material such as plastic, metal, glass or poly vinyl chloride (column 4, line 25). If this connector is applied to the claimed invention, it has to go within the arterial inlet end of the graft of the claimed invention, the catheter in the connector will stay on the side of arterial inlet end of the graft. Park's connector cannot be connected to the venous outflow catheter because the catheter remains on the inlet side not on the outlet side. There will be obstruction, turbulence of the laminar blood flow resulting in thrombosis and destruction of the function of the claimed invention and Squitieri's art. The claimed invention would be inoperable for its intended purpose (In Re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)) The appeal's board made an error in applying a Park's invention to claimed invention.
2. Twardowski's catheter is a double lumen catheter. The claimed invention and Squitieri's invention has a single lumen outflow catheter. One skilled in the art will not combine the two as the two will not fit together and therefore will not enable a person skilled in the art to make claimed invention. The requirements of USC 35, section 112, are not met. The appeal's board made an error in combining Twardowski's and Squitieri's art.
3. Squitieri's art cannot be modified to change the catheter to the right side of the heart as that of claimed invention because there is no teaching in Squitieri's art for modification. The law requires that there must be some teaching in the prior art. (MPEP 2143.01 in re Kahn, 441 F.3d, 977, 986, 78 USPQ 2d 1329, 1335 (Fed Cir. 2006)) The appeals board overlooked this fact.
4. The examiner did not show any advantage or expected beneficial results resulting from the modification of the Squitieri's art (Sernacker, 702 F.2d 989, 994-95, 217 USPQ 1,5-6 (Fed Cir 1983)).
5. Squitieri's art only suggests that the catheter be placed in the vein (see claim 1, claim 8, claim 16) and also suggests any modification be made within the scope of the claims.  
In the absence of teaching, advantage, suggestion, one skilled in the art will not

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be motivated to modify Squitieri's art. The appeals board made an error in modifying Squirieri's art.

6. The principles of operation of claimed invention involves deposition of dialyzed shunt arterial blood into the right atrium of the heart, whereas in Squitieri's art the shunt dialyzed blood is deposited in the vein and in Twardowski's hemodialysis catheter, venous dialyzed blood goes into the right atrium. Combining the teaching of Squitieri's art and Twardowski's art will result in change of principle of operation. The teachings of the references are not sufficient to render the claimed invention prima facie obvious because of the change of principle of operation( In Re Ratti, 270 F.2d 810,123 USPQ 349 (CCPA 1959)) .
7. The examiner did not show some objective reason to combine the teachings of the references of Squitieri, Parks and Twardowski.(Ex Parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)).
8. Examiner misapplied the law (In Re Keller, 642 F.2d 413, 209 USPQ 871 (CCPA 1981)) stating that Squitieri and Twardowski's devices may not be combinable under the Re Keller law. In the instant case combined teaching suggests the placement of catheter in the right atrium to treat the blood to the patient. The law is misapplied, as the treated blood will be of catheter dialysis, not the shunt dialysis of the claimed invention and therefore, the specific function of the claimed invention is not met because arterialized shunt blood will not be used for dialysis. Only the catheter venous blood will be used for dialysis.
9. The cuff of the claimed invention is made of other biocompatible material as is clear in amended claim 7 and also the venous outflow catheter is connected to the graft by surgical anastomosis over cuff (see specification column 3[0049] and abstract disclosure of the patent application). Evidently, the cuff is on the venous outflow catheter with a smooth inner surface.
10. Claimed invention was copied by a company called Hemisphere, Inc. as a device called HeRO vascular Access device. The results carried by two studies of Dr. Katzman and Chris Stout demonstrated the superior results in terms of patency and infection rate and unexpected results in terms of adequacy of dialysis and mortality and successful placement of venous outflow catheter in central vein occlusions by Chris Stout in 50 patients out of 52. As the claimed invention was identical to the HeRO vascular access device The results obtained from the HeRO vascular access device were applicable to the claimed invention under the doctrine of equivalency. The appellants made a declaration that the results are applicable to claimed invention. The claimed invention results cannot be compared with Squitieri's art because Squitieri's art did not go to clinical trials to the best knowledge of the applicant. The executed declaration in support of the application was sent to the examiner, Leslie R. Deak via fax on April 16<sup>th</sup> 2009

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and via mail received by USPTO on April 23<sup>rd</sup>, 2009. It appears that declaration was not sent by examiner to the appeals board. I, Dr. Nazir Khan discussed with the examiner, Leslie Deak, the unexpected results applicable to claimed invention on 10<sup>th</sup> August 2009. Examiner agreed to give careful consideration at appeal conference. The examiner mentioned in appeal brief reply that claimed invention tend to show improved patency and reduced infection rate indicating the improved properties of claimed invention. The examiner be directed to present before appeals board copy of executed declaration. A copy of the return receipt and the telephonic interview with the examiner are enclosed. Another signed copy of the declaration is also enclosed.

The appellants request that the rejection to claim 17 be reconsidered.

An early date for re-hearing is requested because of the special status of the application granted by the board and because of the infringement of the invention.

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**Declaration in Support of Application**

1. We are the applicants in the above identified patent application
2. We declare the HERO<sup>™</sup> (Hemodialysis Reliable Outflow) vascular access device, manufactured by Hemisphere Inc. company is a hemodialysis arteriovenous shunt identical to the applicants claimed invention. Clinical studies revealed new and unexpected results.

These results are a marked decrease in bacteremia rate versus currently used cuffed tunneled dialysis catheters and current arteriovenous graft literature.

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Improved adequacy of dialysis and patency versus currently used cuffed tunneled dialysis catheters.

Please see Exhibit 1 and Exhibit 2 as supporting documents for the HERO™ device.

In patients with central venous occlusion, the HERO™ device has achieved a success rate for allowing dialysis in patients with no other option, 96.2% of the time (50/52 patients).

3. I declare that all of the statements made herein of my knowledge are true and that all statements made upon information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing therefrom.

Respectfully,



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**Fax USPTO  
571-273-8300**

OCT 25 2010

<b>Interview Summary</b>	Application No.	Applicant(s)	
	10/812,380	KHAN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

All participants (applicant, applicant's representative, PTO personnel):

(1) LESLIE R. DEAK. (3) \_\_\_\_\_

(2) Dr. Khan, Applicant. (4) \_\_\_\_\_

Date of Interview: 10 August 2009.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: 1 and 13.

Identification of prior art discussed: Squitieri, Trertola, Twardowski, Parks.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner advised Applicant that claims as presented 28 April 2008 are the claims that will be sent to appeal, since amendments that alter the scope of the claim are not permitted prior to appeal. Applicant reiterated his arguments drawn to the combination of the cited references, as well as the secondary considerations and unexpected results of the instantly claimed invention. The Examiner noted these arguments as presented in the Appeal Brief filed in May 2009, and agreed to give these arguments careful consideration at an upcoming Appeal Conference.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Leslie R. Deak/ Primary Examiner, Art Unit 3761	
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